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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,893	02/02/2000	Stephen J. Brown	HERO-1-1089	6810

25315 7590 12/03/2001

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/03/2001

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/496,893

Applicant(s)

Brown

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 27, 2001

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the applica

~~15 of the above~~ Claim(s) 21-29 have been canceled.

~~is/are withdrawn from consideration~~

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

The request, filed 8/27/01, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/496,893 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments, filed 8/27/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. It is also noted that there is no specific relationship defined regarding "related" application serial number 08/946,341.

The title of the invention is not descriptive. A new title

is required that is clearly indicative of the invention to which the claims are directed. The pending claims are directed to methods for identifying a disease-influencing gene or substance whereas the present title lacks any indication of this method and thus is confusingly different from the claimed invention subject matter.

Claims 1-20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic

engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is reiterated and maintained from the previous office action, mailed 2/27/01. The non-enabled determination of a relationship between a physiologic characteristic and a genotype as required in step j) of claim 1, for example, is now present in the claims. This is also required in claim 10, steps k) and l), wherein a disease-influencing gene is identified via a genotype difference. Similarly, claim 19, step k), indicates the finding of a disease-influencing substance from classes of individuals. Applicant argues that "nonclaimed elements" which are not necessary to the operation of a device need not be disclosed. In response, the above elements are clearly claimed. Thus, the "nonclaimed elements" argument is not directed to the basis of the rejection and is thus moot. It is reiterated from the previous office action, mailed 2/27/01, that the finding of a new genotype which is related to a disease is frequently and most commonly a massive research effort. This undue experimentation also applies to disease-influencing substances as to their relationship or correlation to a disease. Therefore, the instant claims still are deemed to require the relating or correlating of at least one gene or gene segment, or substance to some disease phenotype which still require the above

noted massive research effort for said relating or correlating even if only one gene or disease is to be identified out of the myriad of genes in an individual.

Another lack of enablement issue is that nothing is stated as to the number of individuals which are analyzed or categorized in the practice of the claims. It is well known that a correlation between a gene and a disease or phenotype must be based on a large sampling of individuals and that arbitrary sized samplings for such a purpose are speculative and unpredictable as to result. Since the number of studied individuals in the instant claims is arbitrary and undefined, unpredictable results are expected from such studies and supports this added issue regarding lack of enablement.

Claims 1-20 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step a), individuals are selected which have a risk factor for a disease. These individuals are apparently those which are then utilized in steps b) - l), all of which are at risk, as noted in step a). In step j) a physiologic characteristic is related to a genotype in categories, but yet with all analyzed individuals being at risk. There is apparently no control individuals analyzed which are not at risk for the

disease thus making the claim vague and indefinite as to what specific physiologic and/or genotypic characteristics are to be selected out of the myriad of each that are present in common individuals, such as humans, for example. Additionally, step j), lacks any distinguishing of physiologic characteristic which is different for each of the categories therein cited. It is noted that an implied limitation may be that the related genotype in steps j) and k) are related to different physiologic characteristics in step j) but that "implied" limitations are not deemed clear and concise as required in this statute. Clarification via clearer claim wording is requested. The above unclarities are similarly present in all of the independent claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Martinez, Kauffmann et al., or Schork, in view of the legal decision of In re Venner.

This rejection is reiterated and maintained from the previous office action, mailed 2/27/01. Applicant argues that the specific elements of servers, remotely programmable devices, etc. are not merely the automation of manual activities but lacks any specific reasoning as to why not. For example, applicant argues that data mining is not the automation of a manual activity. In response the above cited references were all summarized previously as directed to the "study of various diseases via inheritance, environmental factors, etc. while suggesting the linking of these data to genetic characteristics with the ultimate goal of some type of drug etc. treatment being possible" (Previous office action, mailed 6/6/00, at page 4, first 5 lines.). This summary indicates "linking" of data as also is instantly claimed as data mining. For example, inheritance is linked to genetic characteristics in said references. This clearly suggests the formation of some type of family tree with inherited disease phenotypes as linked to genetic characteristics (genotypes). These are very specific instructions which are computer programmable. Applicant has not argued or indicated any reason as to what is not directly computer programmable or automatable about such linkage analysis. It is noted that family trees have been available both in popular publications as well as over the internet for many years already at the time of the instant filing date. Given the above cited

references, motivated by large and/or numerous family trees which are clearly available in the popular literature, a computer programmer would be clearly reasonably expected to have success in following the linkage determination procedures in the above references to automate or computerize such procedures given also the recognized obviousness of automating a manual procedure in the legal decision cited as *In re Venner*. Applicant has not stated any specific or distinguishable data mining methodology which is different from the linkage analysis of the cited references. What more does a computer programmer need to automate the procedures in the references? Applicant then argues that reading applicant's invention disclosure is required to practice the instant invention. This argument lacks any distinguishing features or steps over automating the procedures of the cited references via the well known automating obviousness of such manual procedures as noted in *In re Venner*. If applicant believes that some further guidance is required for a programmer to develop a computer program for automating the cited references, then applicant should argue what specifically this required further guidance is. None have been argued, except for data mining, which has already been noted above as being already guided in the linkage of data items in the references. What more is needed? Applicant then confusingly argues inherency and that which is obvious cannot be predicated on what is unknown. It is

noted that inherency is an issue in anticipation rejections which is not the type of rejection discussed here and therefore is an argument which is moot. Also, applicant argues that obviousness cannot be predicted on what is unknown but has not noted anything that is "unknown" in the combination of references with In re Venner as the basis for this rejection. Applicant is also referred to the well known and "old" stories about the hemophilia transmission via genetic inheritance in the royal bloodlines in Europe. Is it applicant's position that this linkage analysis cannot be easily and directly computerized from linkage analysis as supported by the cited references? Applicant then argues that an efficient manner of identifying a gene is previously unknown and untaught in the prior art. In response, computers have been well known for decades to be useful in increasing the computation speed over a corresponding manual process. Thus automating a manual process clearly has a reasonable expectation of success for being more efficient than the manual process on which it is based.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 30, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER